

REMARKS

The remarks herein are responsive to the non-final Office Action dated 9 December 2008. Upon entry of the foregoing amendments, Claims 1-2 and 4-44 remain pending. Claim 1 has been amended. New Claims 45 and 46 have been added.

Additionally, Applicants respectfully submit the comments provided in the attached declaration from Dr. Vinzenz M. Frauchiger. The declaration generally discusses the historical background of the invention and the inoperability of the prior art combinations proposed in the Office Action.

Response to Arguments

In response to Applicants' previous arguments, the Office Action first argues that U.S. Patent No. 5,456,723 ("Steinemann") discloses "a porous metallic biocompatible surface, treated with a reducing acid to be provided with microroughness." Office Action, pages 2-3. However, the "pores" of Steinemann are provided by sandblasting, so these "pores" are pits. Thus, the microroughness of Steinemann (described therein as "pits") is applied over pits. This clarifies that the "pores" of Steinemann (which are pits) and the claimed open pores are distinct.¹

Next, the Office Action argues, generally, that U.S. Patent No. 3,855,638 ("Pilliar") and Steinemann do not teach away from each other because the features allegedly analogous to Pilliar and Steinemann "are distinct throughout Applicant's specification and claims" and that "[a]pplying the pits of Steinemann to the open-pored implant surface of Pilliar teaches the invention precisely as claimed." Office Action, page 3. Applicants disagree with the Office Action's interpretation of the above-captioned application and the Office Action's assertion that Steinemann and Pilliar teach the invention as claimed. Applicants also note that using the application's specification and claims to justify combining prior art references approaches the definition of hindsight bias. Similarly, Applicants disagree with the Office Action's assertion that, "[i]t is appropriate to combine [the features of Steinemann and Rowe] as this is the claimed invention." Office Action, page 4.

The Office Action also argues that the features of Pilliar and Steinemann are distinct in Pilliar and Steinemann. However, in the context of Pilliar and Steinemann the combined features

¹ Applicants interpret the Office Action to acknowledge that the claimed open pores are distinct from the "pits," as described in Steinemann.

are generally equivalent. Both Pilliar and Steinemann rely on their open pores and microroughness as equivalent mechanisms for bone-implant bonding. The perceived equivalence of these features is evidenced by Steinemann's discussion of Pilliar-like references as inferior alternatives, further discussed below. *See, e.g.*, Steinemann at (6:29-33).

Similarly, the Office Action argues that the features of Steinemann and Rowe are distinct because they are at different scales. However, in each reference scale is critical. The Office Action also argues that "Steinemann is not directed to allowing ingrowth of tissue" to distinguish the features of Rowe. However, this argument is made in hindsight, as the Office Action fails to provide support for this distinction and the disclosure of Steinemann appears to indicate the contrary. *See, e.g.*, Steinemann at (4:29-37) (describing each method as allowing "intergrowth").

Rejections of Claims Under 35 U.S.C. § 103

Claims 1, 2, 4-8, 10-12, 15-32, 37-42, and 44

Claims 1, 2, 4-8, 10-12, 15-32, 37-42, and 44 stand rejected under 35 U.S.C. § 103 as being unpatentable over at least Pilliar in view of Steinemann. The subject matter of each reference has been discussed in previous communications.

Regarding Steinemann individually, Applicants respectfully submit that Steinemann does not teach a porous surface with a surface roughness of 2 μm or less. As discussed above, Applicants submit that the "pores" of Steinemann are actually pits and are thus distinct from the pores as claimed.

Further, Applicants respectfully submit that the combination of Pilliar and Steinemann is improper as it would not be obvious to combine the references, the references teach away from each other, and the combination would be inoperable, as described above and in the attached Declaration by Dr. Vinzenz Frauchiger, who has substantial experience in the area of biomedical materials research, including the research and development of implant surfaces in contact with hard and soft tissue.

First, Applicants submit that one of skill in the art at the time of the invention would not be motivated to combine Pilliar and Steinemann. Pilliar promotes large open-pores while Steinemann promotes a small roughening. As each idea promotes a different scale of

roughening, the limited independent success of each idea was previously considered contradictory. Dr. Frauchiger noted that, “[a]bsent a deeper understanding of each method’s underlying mechanisms, one of ordinary skill had no motivation to combine the two.” Frauchiger Declaration at ¶9. For example, Steinemann describes its results as “stand[ing] in perfect contrast to opinions expressed so far in literature [such as those requiring] a contact surface roughness of more than 20 μm .” Pilliar is an example of such contrasted literature. *See*, Pilliar at (3:51-54). As stated by Dr. Frauchiger, “[f]or almost 20 years [these] two contradictory ideas developed independently.” Frauchiger Declaration at ¶9.

As realized by the Applicants, the open pores and submicron roughness provide completely different mechanisms for binding bone with the implant surface. Large open pores such as those in Pilliar allow bone tissue to grow into the implant surface through the pores, creating a stronger interlocking mechanical connection between the bone and the implant. Dr. Frauchiger notes that the “non-open... sandblasted pits of Steinemann would not provide the same functionality.” Frauchiger Declaration at ¶11. However, the smaller surface features of Steinemann allow bone cells to grow onto and adhere to the surface on a microscopic scale.

As noted by Dr. Frauchiger, both of these ideas were known at the time of the invention, but their combination was not considered. Steinemann specifically addressed the large-pore techniques of Pilliar, but did not consider the combination now proposed in the Office Action. Instead Steinemann distinguished these techniques, indicating that those of skill in the art at the time lacked motivation to combine the techniques. *See, e.g.*, Frauchiger Declaration at ¶¶9, 14. Thus, Applicants submit that the combination of Pilliar and Steinemann is improper.

Further, Steinemann and Pilliar teach away from each other. As discussed in previous communications, Pilliar finds it “**essential** that the interstitial pore size exceed about 50 microns.” Pilliar at (3:52-54) (emphasis added). To the contrary, according to Steinemann: “a porous contact surface on a metallic implant is able to... [make] the mating bone intergrow with the implant along the contact surface and speedily form a strong and durable bond, **provided that** the contact surface displays a micro-roughness with pits of the order of magnitude of 2 μm .” Steinemann at (3:19-24) (emphasis added). The ranges in Pilliar and Steinemann conflict. Further, as discussed above and in previous communications, Steinemann specifically contrasts

its own method with methods such as that in Pilliar. Both Pilliar and Steinemann place significant importance on the sizing of their roughness. Because (1) their prescribed roughness sizes are mutually exclusive and (2) Steinemann specifically distinguishes its method from those such as Pilliar, the references teach against each other and their combination is improper. As noted by the Supreme Court's decision in *KSR Int'l. v. Teleflex, Inc.*, a finding of nonobviousness is more likely when the prior art references teach away from a combination of elements. See *KSR Int'l. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740 (2007).

Regarding independent Claim 37, Applicants additionally note that Steinemann teaches away from "a vacuum plasma spraying process," as recited in the claim. For example, according to Steinemann, "the mechanically brittle plasma layer has a tendency to break or peel off." Steinemann at (2:4-5). Further, Steinemann specifically contrasts its method with those achieved by plasma coats. Steinemann at (6:24-27). This provides additional reasons why the combination is improper.

Finally, Applicants respectfully submit that the proposed combination of Pilliar and Steinemann would be inoperable. Steinemann describes a strong etch of the implant surface using a reducing acid. Steinemann at (5:19-27). This acid etch is "strong enough to severely damage, and to a degree destroy, the surface of Pilliar. Accordingly, a combination of Steinemann with Pilliar would essentially result in a surface resembling that of Steinemann alone." Frauchiger Declaration at ¶14. "Essentially, the particles held within the surface layer prior to the Steinemann etch would become too loosely bound, and there would be a significant risk of particle release into the body after implantat[ion]." *Id.*

For at least the reasons described above and in previous communications, Applicants submit that Claims 1, 2, 6-8, 10-12, 15-20, 22, 26-31, 37, 40-42, and 44 are allowable over Pilliar in view of Steinemann. There would be no motivation for a person of skill in the art to combine Pilliar and Steinemann at the time of invention. Additionally, Pilliar and Steinemann teach away from combination with each other. Further, the combination of Pilliar with Steinemann would be inoperable so that one of ordinary skill in the art would have no reasonable expectation of success in combining Pilliar with Steinemann to achieve the claimed invention. Additionally, as

discussed above and in the previous communications, Applicants submit that the Office Action has not established a prima facie case of obviousness. Applicants further submit that the dependent Claims 2, 6-8, 10-12, 15-20, 22, 26-31, 40-42, and 44 recite unique combinations of features, not taught or suggested by the cited art, and are thus further allowable over the cited art.

Claim 21 stands rejected under 35 U.S.C. § 103 as being unpatentable over Pilliar in view of Steinemann and additionally in view of U.S. Patent No. 4,206,516. Claim 21 depends from independent Claim 8 and the Office Action's analysis is the same. Thus, Applicants respectfully submit that Claim 21 is allowable for at least the same reasons as Claim 8.

Claims 4, 5, 23-25, 32, 38, and 39 stand rejected under 35 U.S.C. § 103 as being unpatentable over Pilliar in view of Steinemann and additionally in view of U.S. Patent Publication No. 2004/0030387. Claims 4, 5, 23-25, 32, 38, and 39 depend from independent Claims 1, 8, and 37 and the Office Action's analysis is the same. Thus, Applicants respectfully submit that Claims 4, 5, 23-25, 32, 38, and 39 are allowable for at least the same reasons as Claims 1, 8, and 37.

Claims 8, 11-14, 17, 18, 20, 22, 26-31, and 42

Claims 8, 11-14, 17, 18, 20, 22, 26-31, and 42 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,034,186 ("Shimamune") in view of Steinemann. Applicants respectfully submit that the combination of Shimamune with Steinemann is improper for reasons similar to those described above. For example, Shimamune embodies the same ideas as Pilliar, which had previously been considered contradictory to the ideas of Steinemann. Frauchiger Declaration at ¶¶9, 11. Further, Shimamune sinters a powder to a substrate. Shimamune at Abstract. As discussed above and in the Declaration by Dr. Frauchiger, the acid etch of Steinemann would destroy such a layer. *Id.*, at ¶14.

For at least the reasons described above and in previous communications, Applicants submit that Claims 8, 11-14, 17, 18, 20, 22, 26-31, and 42 are allowable over Shimamune in view of Steinemann. There would be no motivation for a person of skill in the art to combine Shimamune and Steinemann at the time of invention. Additionally, Shimamune and Steinemann teach away from combination with each other. Further, the combination of Shimamune with Steinemann would be inoperable so that one of ordinary skill in the art would have no reasonable

expectation of success in combining Shimamune with Steinemann to achieve the claimed invention. Applicants further submit that the dependent Claims 11-14, 17, 18, 20, 22, 26-31, and 42 recite unique combinations of features, not taught or suggested by the cited art, and are thus further allowable over the cited art.

Claims 8, 9, 33-36, and 43

Claims 8, 9, 33-35, and 43 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,542,539 ("Rowe") in view of Steinemann. Applicants respectfully submit that the combination of Rowe with Steinemann is improper for reasons similar to those described above. For example, Rowe embodies the same ideas as Pilliar, which had previously been considered contradictory to the ideas of Steinemann. Frauchiger Declaration at ¶9, 11. Further, Rowe uses a flame-plasma process to apply materials to a substrate. Rowe at (5:45-49). As discussed above, the acid etch of Steinemann would destroy such a layer. *Id.*, at ¶14. Additionally, Rowe uses a pore size range between 100 and 500 micrometers, much larger than the upper limit of Steinemann. Rowe at (5:38-40).

For at least the reasons described above and in previous communications, Applicants submit that Claims 8, 9, 33-35, and 43 are allowable over Rowe in view of Steinemann. There would be no motivation for a person of skill in the art to combine Rowe and Steinemann at the time of invention. Additionally, Rowe and Steinemann teach away from combination with each other. Further, the combination of Rowe with Steinemann would be inoperable so that one of ordinary skill in the art would have no reasonable expectation of success in combining Rowe with Steinemann to achieve the claimed invention. Applicants further submit that the dependent Claims 11-14, 17, 18, 20, 22, 26-31, and 42 recite unique combinations of features, not taught or suggested by the cited art, and are thus further allowable over the cited art.

Claim 36 stands rejected under 35 U.S.C. § 103 as being unpatentable over Rowe in view of Steinemann and additionally in view of U.S. Patent Publication No. 2007/0030387. Claim 36 depends from independent Claim 33 and the Office Action's analysis is the same. Thus, Applicants respectfully submit that Claim 21 is allowable for at least the same reasons as Claim 8.

Application No.: 10/519,338
Filing Date: September 19, 2005

Claim Amendments and New Claims

Claim 1 has been amended to clarify the claimed subject matter and has not been amended for purposes of patentability. Claims 45 and 46 have been added. Support for the new claims is at least at paragraphs [0020] and [0039] of the originally filed specification. No new matter has been added by these amendments.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

| Serial Number | Title | Filed |
|---------------|---|------------|
| 11/722,697 | A METHOD OF SURFACE FINISHING A BONE IMPLANT | 12/22/2005 |
| 12/092,545 | OPEN-PORE BIOCOMPATIBLE SURFACE LAYER FOR AN IMPLANT, METHODS OF PRODUCTION AND USE | 5/2/2008 |

CONCLUSION

For at least the forgoing reasons, the Applicants believes that Claims 1-2 and 4-46 are allowable over the art of record and are in condition for immediate allowance.

The Applicants respectfully submit that any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any

Application No.: 10/519,338
Filing Date: September 19, 2005

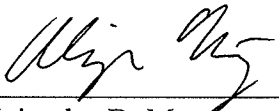
remarks referring to only a portion of a claim should not be understood to base patentability on that portion or that the limitation discussed is essential or critical; rather, patentability must rest on each claim taken as a whole. The Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence, disclaimer or estoppel is intended or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. The Applicants may not have presented in all cases, all arguments concerning whether the applied references can be properly combined or modified in view of the deficiencies noted above, and Applicants reserve the right to later contest whether the cited references can be properly combined or modified.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 9, 2009

By: 
Alejandro D. Munoz
Registration No. 63,534
Attorney of Record
Customer No. 20995
(949) 760-0404

AMEND

6832104_2
040809